

REQUEST FOR RECONSIDERATION

Claims 6-13 remain active in this application.

The claimed invention is directed to a food product comprising an oil composition and food.

Diglyceride compositions have gained interest based on a disclosed obesity-preventing effect. In addition, ω 3 type unsaturated fatty acids having at least 20 carbon atoms such as docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), principle components of fish oil triglycerides, have been reported to have beneficial health properties. ω 3 Type unsaturated fatty acid have been reported to have very poor oxidation stability (page 2, lines 17-19 of the specification) while diglycerides of ω 3 type unsaturated fatty acids have exhibited very high viscosities (page 2, line 27 through page 3, line 5 of the specification). Accordingly, diglyceride containing compositions of ω 3 unsaturated fatty acids having good stability and viscosity are sought.

The claimed invention addresses this problem by providing a food product comprising an oil composition and food comprising 0.1 to 59.8 wt. % of triglyceride, about 40 to 99.7 wt. % of diglyceride and 0.1 to 10 wt. % of monoglyceride, wherein the diglyceride component has 15-89.5 wt. % of ω 3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups. Applicants have discovered that an oil composition comprising triglyceride, diglyceride and monoglyceride wherein the diglyceride has such a distribution of ω 3 unsaturated fatty acids and monoenoic acyl groups provide for an oil composition having **good stability and viscosity**. Such a composition is nowhere disclosed or suggested in the cited and applied prior art of record.

The rejection of claims 6 under 35 U.S.C. § 103(a) over Howard et al. (U.S. 3,267,337) is respectfully traversed.

Howard et al. fail to disclose or suggest the claimed food product in which the oil composition comprised triglyceride, diglyceride and monoglyceride wherein the diglyceride is comprised of 15 to 89.5 wt. % of ω 3 unsaturated acyl groups and 10 to 84.5 wt. % monoenoic acyl groups.

Howard et al. describe an edible composition comprising starch, shortening and sugar as well as an alpha-phase crystal-tending emulsifier (column 2, lines 45-50). The α -phase crystal-tending emulsified may be a diglyceride of a 1,3-, 1,2- or mixture of 1,3- and 1,2-diglyceride (column 4, lines 13-20). The 1,3-diglyceride is composed of an acyl group with C₂₋₄ carbon atoms as one acyl group and C₁₆₋₂₂ carbon atoms on the other while the 1,2-diglyceride is composed of an acyl group with C₁₂₋₁₈ carbon atoms as one acyl group and C₁₆₋₂₂ carbon atoms on the other (column 4, lines 15-23). The reference merely describes chain length of the acyl groups and there is **no disclosure** as to the content of ω 3 unsaturated acyl groups and monoenoic acyl groups.

At column 9 is a description of a **shortening**, a **triglyceride**, which may be based on animal, vegetable or marine fats and oils and may bear saturated or unsaturated acyl groups of about 12-22 carbon atoms (lines 5-31). This portion of the reference describes chain length and the possibility of unsaturation but fails to describe a **diglyceride**.

Accordingly the reference provides separate descriptions of an emulsifier based on 1,3- and 1,2-diglycerides in the absence of a description of a content of ω 3 unsaturated acyl groups and monoenoic acyl groups as well as a shortening bearing saturated and unsaturated acyl groups in the absence of a description of diglycerides.

No Motivation To Form Oil Composition Comprising 40-99.7 wt. % of Diglyceride Having Specific Content Of ω 3 Unsaturated Acyl Groups And Monoenoic Acyl Groups

The emulsifier component and the shortening component are **separate components** of the layer cake. It is clear that the shorting component does not principally contain diglyceride in so far as the reference provides for the shortening containing “minor amounts of conventional cake emulsifier such as the higher fatty acid mono-diglycerides” (column 9, lines 30-31). Thus there is no suggestion that the shortening component contain 40-99.7 wt. % of diglyceride. This makes clear that the description of saturated and unsaturated acyl groups (column 9, lines 9-11) refers to triglyceride oils and not 40-99.7 wt.% diglyceride oils.

Accordingly, since the reference provides separate disclosures as to the emulsifier component and the shortening component there is no motivation to provide an oil component having 40-99.7 wt % of diglyceride having specified content of ω 3 unsaturated acyl groups and 10 to 84.5 wt. % monoenoic acyl groups. The reasoning is that the reference describes an emulsifier containing diglyceride but fails to describe ω 3 unsaturated acyl groups and monoenoic acyl groups. Conversely the reference also describes a shortening composition containing principally triglyceride based on saturated and unsaturated fatty acids, but fails to describe diglycerides.

Accordingly, there is no disclosure of an oil composition comprising about 40 to 99.7 wt. % of diglyceride wherein the diglyceride component has 15-89.5 wt. % of ω 3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt.% of monoenoic acyl groups.

In contrast, the claimed invention is directed to a food product comprising an oil composition and food wherein the oil component comprises about 40 to 99.7 wt. % of diglyceride wherein the diglyceride component has 15-89.5 wt. % of ω 3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups.

*Description Of Acyl Groups From Rapeseed Oil Does Not Suggest 15-89.5 Wt. % Of
ω3 Unsaturated Acyl Group Having At Least 20 Carbon Atoms With 10-84.5 Wt% Of
Monoenoic Acyl Groups*

The examiner has apparently equated applicants' use of rapeseed oil as a source of acyl groups in the preparation of a diglyceride oil as claimed as basis to infer that the claimed distribution of 15-89.5 wt. % of ω3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups is somehow inherent to the use of rapeseed oil.

Applicants note that applicants' specification describes the preparation of diglyceride by

Transesterification of any of various oils such as fish oil and rapeseed oil containing ω3 unsaturated acyl groups, monoenoic acyl groups, ω6 type unsaturated acyl groups etc. with glycerol. (column 6, line 24 through page 7, line 3)

During the process of transesterification, ester groups are transferred among the glycerin molecules from the fish oil and from the rapeseed oil. Introduction of a high concentration of ω3 unsaturated acyl groups from the fish oil would preclude a conclusion that the claimed distribution of ω3 unsaturated acyl groups having at least 20 carbon atoms and of monoenoic acyl groups to be inherent to rapeseed oil.

Accordingly the mere description of acyl groups from rapeseed oil (column 9, line 17 of Howard) fails to suggest the claimed 15-89.5 wt. % of ω3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups as such a distribution of unsaturated acyl groups has not been show to be inherent to the use of rapeseed oil alone.

Further, the claimed 15-89.5 wt. % of ω3 unsaturated acyl group having at least 20 carbon atoms with 10-84.5 wt% of monoenoic acyl groups would not have been obvious based on the disclosure of Howard as the reference fails to suggest anything about ω3 unsaturated acyl group having at least 20 carbon atoms or monoenoic acyl groups. The

claimed distribution can not be rendered obvious in the absence of any disclosure of ω 3 unsaturated acyl group having at least 20 carbon atoms or monoenoic acyl groups.

As the cited reference fails to disclose the claim limitation of 40-99.7 wt. % of diglyceride containing ω 3 unsaturated acyl group having at least 20 carbon atoms and monoenoic acyl groups, the claimed invention would not have been rendered obvious by this reference and withdrawal of the rejection under 35 U.S.C. §103(a) based on Howard et al. is respectfully requested.

The rejection of claims 6-13 under 35 U.S.C. 103(a) over Volpenhein U.S. 4,263,216 and Stout et al. U.S. 5,149,851 in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Ciani J. Sci. Food Agric. 1998, 78; 290-0294, in view of Young et al. U.S. 5,085,884 is respectfully traversed.

None of the cited references disclose a food composition comprising an oil composition comprising 40 to 99.7 wt. % of diglyceride containing ω 3 unsaturated acyl group having at least 20 carbon atoms and monoenoic acyl groups, as claimed.

Volpenhein merely describes the preparation of **saturated diglycerides** (column 3, lines 53-55) as an intermediate toward the manufacture of confectioner's cocoa butter (column 4, lines 43-45). The saturated diglyceride is converted by esterification of the 2-position in order to provide triglyceride mixtures which are useful as confectioner's hard butter, and the like (column 1, lines 6-11). Accordingly, at best the reference describes saturated diglycerides as **intermediates** in the preparation of triglycerides which are useful as confectioner's cocoa butter. This reference is deficient in failing to 1) describe the claimed oil composition comprising 40 to 99.7 wt. % of diglyceride containing ω 3 unsaturated acyl group having at least 20 carbon atoms and monoenoic acyl groups; and 2) failing to provide a utility for the diglyceride other than as an intermediate in the production of a useful triglyceride.

Stout et al is also flawed in failing to disclose or suggest the claimed unsaturated diglycerides.

Stout et al describes the preparation of **triglycerides** containing unsaturated fatty acid residues, by the reaction of esters of such fatty acids with glycerol (column 2, lines 51-55). The reference describes the desirable nature of ω 3 unsaturated acyl groups (column 2, lines 6-16) but in the form of triglyceride compositions, a form which maximizes the number of ω 3 unsaturated acyl groups being delivered.

No Motivation To Modify The Saturated Diglyceride Composition of Volpenhein

Volpenhein simply describes saturated diglyceride composition as intermediates to the preparation of useful triglyceride compounds. There is no other utility suggested for these saturated diglycerides. Therefore, there would be no motivation to modify the saturated diglycerides of Volpenhein since the saturated diglycerides are only known as reaction intermediates.

Similarly, if the prior art merely discloses compounds as intermediates in the production of a final product, one of ordinary skill in the art would not have been motivated to stop the reference synthesis and investigate the intermediate compounds with an expectation of arriving at claimed compounds which have different uses. *In re Lahu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). (M.P.E.P §2144.09)

As the cited reference only describes saturated diglycerides as an intermediate toward the preparation of useful triglycerides, there would have been no motivation to modify the saturated diglycerides to obtain the unsaturated diglycerides as claimed.

No Motivation to Modify The Unsaturated Triglycerides of Stout et al As Diglyceride Reduces The Unsaturated Fatty Acid Content

While not specifically articulated by the examiner as a basis for obviousness, the unsaturated triglycerides of Stout et al. fail to render obvious the claimed food composition

comprising unsaturated diglyceride as a diglyceride has a reduced unsaturated fatty acid content relative to a triglyceride.

Stout et al. describes the desirability of polyunsaturated free fatty acids and identifies triglycerides of polyunsaturated free fatty acids as an obvious alternative to polyunsaturated free fatty acids which are easily autoxidized (column 2, lines 16-27). The triglyceride is chosen for the high content of the unsaturated fatty acid (column 2, lines 25-27). Since a diglyceride has 33% less unsaturated fatty acid than a triglyceride, the reference provides no motivation to formulate unsaturated diglycerides.

The secondary references fail to cure the fundamental flaws of the primary references. In spite of applicants' request for clarification, the outstanding rejection fails to articulate, with any clarity, how the combination of primary and secondary references renders the claimed invention obvious.

The examiner's assertion of obviousness from pages 16-17 is as follows:

Based on the teaching of Brown et al of the incorporation of the specific health promoting fatty acids e.g. omega-3 fatty acids such as eicosapentanoic acids, into triglyceride oils and fats (column 1, lines 26-29), someone of skill in the art at the time the instant invention was made **would have been motivated to combine** the teachings of Volpenhein U.S. 4,263,216 and Stout et al. U.S. 5,149,851 in view of Brown et al. U.S. 5,288,619, in view of Seiden et al. U.S. 4,680,184, in view of Ainger et al. U.S. 4,214,012, in view of Ciani *J. Sci. Food Agric.* 1998, 78; 290-0294, in view of Young et al. U.S. 5,085,884, **to create the instant inventive concept.** (emphasis added)

Such an assertion as to obviousness fails to satisfy the **examiner's burden** to indicate (B) the difference or differences in the claim over the applied reference(s), (C) the proposed modification of the applied reference(s) necessary to arrive at the **claimed** subject matter, and (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification. (emphasis added) (M.P.E.P. §706.02(j)). In short the examiner has failed to provide any indication as to the obviousness of the claimed invention but rather merely asserts a motivation to create "the instant inventive

concept.” Since the instant inventive concept as understood by the examiner is not clear, the examiner has clearly not met his burden of proof of establishing a *prima facie* case of obviousness of the **claimed invention**.

On page 17 of the outstanding official action, the examiner asserts that *KSR* forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness.

The examiner’s attention is directed to M.P.E.P. section § 2143.01 which cites to *KSR* as follows:

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the result would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.* 550 U.S., 82, USPQ2d 1385, 1396 (2007)

Rejections on obviousness cannot be sustained by mere conclusory statement, instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness *KSR International Co. v. Teleflex Inc.* 550 U.S., 82, USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441, F.3d 977, 988, 78 USPQ2d, 1329, 1329 (Fed. Cir. 2006)

Thus, it is clear that motivation is still a requirement in concluding obviousness. As the examiner’s rejection **fails to articulate any rational underpinning** to support the legal conclusion of obviousness, the rejection is improper and must be withdrawn.

While section 2143.02 of the MPEP cites *KSR* as supporting a conclusion of obviousness where the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill, the present claims are still not obvious as the claim element of an unsaturated diglyceride is not demonstrated as known by the cited references. As previously discussed, the cited references only describe **saturated** diglycerides and

unsaturated **triglycerides** and therefore the claimed **unsaturated diglyceride** is not disclosed in the cited references.

The specific deficiencies of the secondary references are addressed as follows:

Brown et al. merely describes the preparation of a **hydrogenated** transesterified stearic acid or stearic acid monoester triglyceride (see Abstract). As a result of hydrogenation unsaturation units as claimed should be destroyed. The reference fails to disclose or suggest the claimed unsaturated acyl groups in a diglyceride.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Seiden et al. describes an emulsifier for cookies comprising fatty acid mono-diglycerides, fatty acid esters of polyols and fatty acid monoglyceride esters of polycarboxylic acids (see abstract). There is no disclosure as to ω 3 unsaturated acyl groups having at least 20 carbon atoms nor monoenoic acyl groups.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Ainger et al. is direct to a confectioner's butter substitute (column 3, lines 22-25) which comprises unsaturated fatty acids, but fails to suggest a composition comprising triglyceride, diglycerides and monoglycerides in the amounts claimed.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Ciani merely describes components of food compositions and fail to disclose or suggest the claimed monoenoic acyl group claim limitation.

Even though it is not clear how this reference is being applied in support of the examiner's case of obviousness, Young et al. describes a nondigestible fat comprising a nondigestible oil and solid polyol fatty acid polyesters having unsaturated ester groups (see abstract). There is no suggestion of the claimed oil composition comprising triglyceride, diglyceride and monoglyceride.

The objection to the specification as to pages 6, 8, 10, 12, 17, 23, 24 and 28 does not need to be addressed as the asserted missing/eligible information and/or extraneous markings on the pages has not obscured the accurate reproduction by the U.S.P.T.O. in the published application 2004/0151824 in paragraphs [0013], [0017], [0019], [0023], [0034], [0048], [0049] and [0062]. As applicants' specification was certainly legible enough for the U.S.P.T.O. to publish applicants' specification, no replacement pages are believed to be necessary. Nonetheless, applicants attach hereto copies of pages 6, 8, 10, 12, 17, 23, 24 and 28 **as filed**. These pages are **not correction** of defective pages because applicants' pages were correct as filed. The defects were introduced by the USPTO.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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